1626

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PTO/SB/21 (08-00)
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Application Number	09/980,243
Filing Date	11/29/2001
First Named Inventor	Freund, et al.
Group Art Unit	1626
Examiner Name	Rebecca Anderson
Total Number of Pages in This Submission	8
Attorney Docket Number	LeA 33 469

ENCLOSURES *(check all that apply)*

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- [ ] Amendment / Reply
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  - [ ] Affidavits/declaration(s)
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Response to Restriction Requirement

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Date	**January 9, 2003**	

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Attorney Docket No. LeA 33469

#6 m.m. 1/30/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Freund, et al.

Serial No: 09/980,243

Filed: 11/29/2001

For: Substituted Phenylcyclohexanecarboxamides

Group Art Unit: 1626

Examiner: Rebecca Anderson

CERTIFICATION OF MAILING UNDER 37 C.F.R. 1.8(a)

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Date: JAN 9 2003

Beatriz Alviz

Response to Restriction Requirement

Assistant Commissioner for Patents

Washington, DC 20231

Sir:

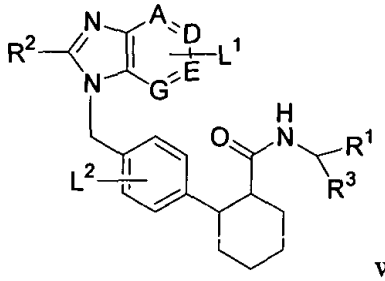
This is in response to the Official Action dated 10/11/02.

In the Official Action, the examiner outlined eight "exemplary" restriction groups, required the applicants "to elect a single invention to which the claims must be restricted", and stated that "applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and the examiner will endeavor to group the same".

In accordance with the examiner's offer to allow the applicants to identify a specific embodiment other than one of the eight exemplary restriction groups presented by the examiner, the applicants suggest that prosecution in this application be continued on the basis of the following restriction group, now identified as suggested restriction group IX. This is quite similar to the examiner's exemplary restriction group IV, but not identical, as will be apparent.

Suggested restriction group IX:

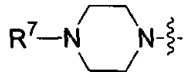
Compounds of the formula



wherein

A is CH, D is CH, E is CH, and G is CH ;

R^1 is C(O)-NR^4R^5 wherein R^4 and R^5 are independently H or $(C_1\text{-}C_6)$alkyl (as defined in claim 1);

R^2 is  optionally substituted by 1-3 OH groups and/or by NR^8R^9 ,

wherein R^7 is H, $(C_1\text{-}C_6)$alkyl, hydroxy-$(C_1\text{-}C_6)$alkyl, or $(C_3\text{-}C_7)$cycloalkyl, and

R^8 and R^9 are independently H, $(C_1\text{-}C_6)$alkyl, or $(C_3\text{-}C_7)$cycloalkyl (as defined in claim 1),

R^3 is a phenyl or naphthly group optionally substituted as defined in claim 1, and

L^1 and L^2 are as defined in claim 1.

Also included in suggested restriction group IX are pharmaceutical compositions containing these compounds, processes for their preparation, and methods for their use. Claims 1-5, 11, and 15-21 are considered to read on the subject matter of this restriction group.

For the record, applicants do not concede that suggested restriction group IX or any other restriction group which consititues part of the subject matter of Markush claim 1 is a "single

invention", but rather, consider that the invention is the compounds defined by claim 1, plus the pharmaceutical compositions, methods of making, and methods of using the compounds of claim 1. Simply because the Office finds it inconvenient or difficult to deal with a generic claim covering a number of separately patentable subgeneric sets of compounds does not mean that the applicants consider their invention to be anything less than what they claimed.

Applicants agree to proceed with prosecution of subject matter elected in response to a restriction requirement in the interests of facilitating further prosecution of the application, but maintain that restricting a Markush claim is improper under US law, and will be happy to provide citations to the statute and the case law in support of this proposition if the examiner would like to have these.

The examiner states, "The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a cyclohexyl benzimidazole, which does not define a contribution over the prior art (as can be seen by the compounds on page 4 of EP 0725064). The substituents on the cyclohexyl benzimidazole vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter."

The examiner is deemed to have misinterpreted the rules concerning unity of invention in the context of a Markush claim. Under PCT rule 13, where there is more than one invention in a PCT application, these are considered linked so as to form a single general inventive concept only when there is a technical relationship involving one or more of the same or corresponding "special technical features". The expression "special technical features" means those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Annex B of the PCT Administrative Instructions explains the method for determining unity of invention with respect to Markush practice as follows. The requirement of

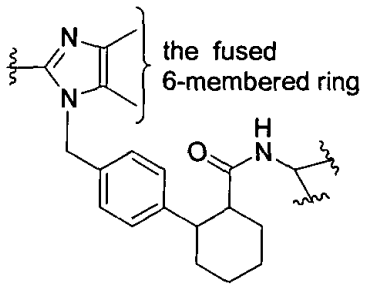
a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2 are considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature if the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present official action, the examiner's statement that the claims lack unity of invention since "the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art" arguably misapprehends the rules regarding Markush claims, set forth above. In the present case, (A) all the claimed compounds are asserted to have a common property or activity, namely, inhibiting adenosine uptake, and (B) a common structure is present, namely,



. This is much more than the cyclohexyl benzimidazole asserted by the examiner, and arguably qualifies as a significant structural element shared by all of the alternative compounds. Accordingly, it is deemed that unity of invention is present for the compounds defined by claim 1. As these compounds are employed in the claimed pharmaceutical compositions, are made by the claimed method of making, and are employed in the claimed methods of use, it is further deemed that unity of invention exists with regard to those different categories of claims.

Respectfully submitted,

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